REMARKS

Reconsideration of this Application is respectfully requested. Pursuant to the present Office Action, Claims 1-8 are amended, without prejudice or disclaimer. Claims 9 and 10 have been withdrawn from consideration by the Examiner and are, therefore, cancelled, also without prejudice or disclaimer. Claims 1-8 remain in this case.

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Initially, in the Office Action, the Examiner acknowledged Applicants' election, but incorrectly states that the Claims elected, namely, Group I, are Claims 1-18, rather than Claims 1-8. She then rejected Claims 1-8 under 35 U.S.C. § 112, Second Paragraph, for indefiniteness. More particularly, the Examiner indicates that while the Claims recite that the enzymes are in about 0.4 ml of "physiological solution", she takes the position that no definition of "physiological solution" is provided, asserting that the term is merely "mentioned" on pages 5 and 8 of the Specification. She, in turn, argues that it is unclear whether Applicants mean that some sort of standard saline solution is being utilized or some other solution appropriate to the storage and use of these enzymes.

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In response, Applicants respectfully state that the term "physiological solution" is considered well-known by those skilled in the art of medical treatments as referring to a solution that is compatible with the body including, but not limited to, e.g., an isosmotic, 0.9 % saline solution. In this regard, Applicants respectfully direct the Examiner to the following Dictionary definitions of the expression "physiological saline" which term, as also indicated, is synonymous with "physiological saline solution":

(1) *physiological saline*: a solution of a salt or salts that is essentially isotonic with tissue fluids or blood; especially : an approximately 0.9 percent solution of sodium chloride called also normal saline solution, normal salt solution, ***physiological saline solution***, physiological salt solution. *See Merriam-Webster's Medical Dictionary, © 2002 Merriam-Webster, Inc.*

(2) *physiological saline*: a sterile solution of sodium chloride that is isotonic to body fluids, used to maintain living tissue temporarily and as a solvent for parenterally administered drugs. *See The American Heritage® Stedman's Medical Dictionary, Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.*

As an aside, Applicants respectfully note that the term "isosmotic", which is referenced by Applicants as being a characteristic property of a "physiological solution", is synonymous with the word "isotonic" referenced in the foregoing definitions of "physiological saline solution". "Isotonic" means: (1) noting or pertaining to solutions characterized by equal osmotic pressure (in Physical Chemistry); (2) noting or pertaining to a solution containing the same salt concentration as mammalian blood (in Physiology). *Dictionary.com Unabridged (v 1.1). Based on the Random House Unabridged Dictionary, © Random House, Inc. 2006.*

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Based on the foregoing, Applicants believe that they have provided appropriate clarification as to the meaning of the term "physiological solution". Withdrawal of the Examiner's rejection under 35 U.S.C. § 112, Second Paragraph, is therefore requested.

* * * * *

Regarding Claims 3 and 7, the Examiner takes the position that although these Claims recite that the enzymes are in "lyophilized form", they do not mention the presence of the "physiological solution" recited in independent Claims 1 and 5. Hence, she determined that it is unclear, in these Claims, whether no "physiological solution" is provided, if such is provided separately in bulk, or if it is provided separately in aliquots for the purpose of effective reconstitution of the enzyme powders.

Similarly, as to Claims 4 and 8, the Examiner argues that they fail to further limit the "kits" of Claims 1 and 5 which, she says, recite kits with enzymes in aliquot parts of "physiological solution". The Examiner explains, although the Claims allegedly recite that the enzymes are in "lyophilized form" in aliquot parts, they do not recite the "physiological solution" as being comprised in separate aliquot parts. Thus, she concludes, the lyophilized enzymes could be present in reconstituted form in the "physiological solution", which she believes is the same as the kit presentations in Claims 1 and 5. Furthermore, she asserts that the amounts of "physiological solution" intended for each enzyme aliquot is unclear. In particular, the Examiner takes the position that if there is a range from 0.4 ml to 7.2 ml, the relationship between the amount of "physiological solution" and the amount of enzyme to be reconstituted is confusing, assuming, she says, that the concentration of the enzyme is important to the use of the kit.

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In response, Applicant respectfully notes that Claims 3, 4, 7 and 8 are amended herein to clarify that the "kit" according to Claims 1 and 5, respectively, "further

comprises" what is set forth in each of the dependent Claims and, therefore, to better define the invention without limiting effect. Applicants respectfully note that the "physiological solution" is, of course, considered generally important for dissolving the enzymes provided in lyophilized form. As Applicants believe they have provided appropriate clarification, withdrawal of the Examiner's rejection of Claims 1-8 under 35 U.S.C. § 112, Second Paragraph, is appropriate.

* * * * *

Finally, the Examiner rejected Claims 5-8 under 35 U.S.C. § 101 on grounds that Applicants have claimed the use of enzymes for the preparation of a pharmaceu-tical kit without setting forth any steps involved in the process of preparing the same. More specifically, according to the Examiner, because the Claims do not set forth any of the steps involved in the method/process of preparing the kit, it is unclear what method/process Applicants are intending to encompass. The Examiner notes that a Claim is indefinite when it merely recites a use without any active, positive steps delimiting how the use is actually practiced. She concludes that Applicants' Claims, as worded, result in an improper definition of a process, i.e., are not proper process Claims under § 101.

* * * * *

Accordingly, Applicants have amended independent Claim 5 to read, in pertinent part, "[a] method of producing a pharmaceutical kit which comprises the enzymes glutathione peroxidase (Enzyme A), prolidase (Enzyme B), glucose-6-phosphate dehydrogenase (Enzyme C) and, optionally, aldose reductase (Enzyme D) for treatment of retinitis pigmentosis by injection into a patient's retrobulbar tissue, the method compri-

sing the steps of providing the enzymes in aliquot parts and in interactive quantities appropriate for administering..."

In claiming a "method of producing a pharmaceutical kit" rather than mere "use of the enzymes..." in the manner described, Applicants submit that they have overcome the Examiner's rejection under 35 U.S.C. § 101.

Withdrawal of this rejection is respectfully requested.

* * * * *

Claims 9 and 10, having been withdrawn from consideration previously by the Examiner, are now cancelled, without prejudice or disclaimer.

In addition, Applicants have undertaken to amend the Specification and the Claims, without prejudice or disclaimer, to further comport with U.S. practice and, in so doing, to better define the invention without limiting effect.

* * * * *

Pursuant to discussions with Examiner Hobbs including the Examiner Interview on this date, Applicants understand that the Examiner has found no references that could anticipate or render obvious Applicants' invention, as claimed.

Applicants respectfully submit that none of the cited references, whether taken alone or in any combination, disclose or suggest Applicants' invention, as claimed. Withdrawal of the Examiner's rejections under §§ 101 and 112, Second Paragraph, is, therefore, respectfully requested.

Applicants have made a good faith attempt to place this Application in condition for allowance. Favorable action is requested. If there is any further point requiring attention prior to allowance, the Examiner is asked to contact Applicants' counsel at (646) 265-1468.

Respectfully submitted,

Dated: April 18, 2008

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, in an envelope with sufficient postage addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

on April 18, 2008

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